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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,174	10/20/2003	Roger Strickland	2979	2714

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Beck & Tysver, P.L.L.C.
Suite 100
2900 Thomas Avenue S.
Minneapolis, MN 55416

EXAMINER	
MITCHELL, TEENA KAY	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/689,174	STRICKLAND ET AL.	
	Examiner	Art Unit	
	Teena Mitchell	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood (6,807,967).

Wood in a nasal cannula (10) for use with a positive air pressure system (Col. 5, lines 54-67 and Col. 6, lines 1-20) said nasal cannula comprising first and second nasal inserts (22, 30) for insertion into a patient's nares (Fig. 1), whereby the area of each insert and the area of the nare are essentially equal so that positive air pressure seal is created between the nare and the insert (Col. 6, lines 30-67 and Col. 7, lines 1-35); a first delivery tube and a second delivery tube (18), each coupled to both of said nasal inserts (Fig. 2A), whereby each nasal insert communicates with both the first delivery tube and second delivery tube; a coupler (12) located remote from said nasal inserts (22) for coupling said cannula to said source of respiration gas; at least one bleed port (38) positioned proximate a nasal insert communicating with said delivery tubes, directly open to atmospheric pressure (Figs. 2A, 4). The difference between Wood and claim 1 is an indentation between the first and second nasal inserts. Applicant has not

disclosed that not having an indentation solves any stated problem or is for any particular purpose. Accordingly the nasal cannla with no indentations between the first and second nasal inserts is deemed to be a design consideration which fails to patentably distinguish over the prior art of Wood.

With respect to claim 2, Wood discloses two tubular bleed ports (Fig. 2A) each having an internal lumen (Fig. 4, 38); each of said tubular bleed ports (38) located directly in line with one of said nasal insert (Fig. 2A) for preferentially intercepting expired gas during an exhalation, said bleed port having an characteristic bleed port diameter (Fig. 4), and separated by a distance (Fig. 2A, Col. 6, lines 59-67 and Col. 7, lines 1-54). With respect to calling the bleed port diameter BPD, such would have been an obvious matter of design consideration as BPD is an acronym for bleed port diameter; also calling the distance between bleed ports L, one of ordinary skill in the art at the time the invention was made would find it an obvious matter of design consideration to call the distance between the bleed ports as L because L represents a term for length well known in the art.

The difference between Wood and claim 3 is Wood is not specific on the amount of carbon dioxide content of inspired air to a value below approximately 0.5% carbon dioxide for the air inhaled from and retained by the delivery tubes. However, Wood does disclose that the internal diameter of the bleeder port is ample to permit venting of carbon dioxide exhaled by the patient while not being so large as to cause a significant pressure drop in the cannula body (Col. 7, lines 14-34). Based on the size of the bleeder ports one of ordinary skill in the art would be able to arrive at a specific value of

below 5% carbon dioxide for the air inhaled and retained by the delivery tubes, as in the respiratory field it is always a concern of retention of CO2.

With respect to claim 4, Wood discloses wherein said nasal inserts (22, 30) terminate in a compliant flange (36) at their distal ends to conform to the nare of a patient.

With respect to claim 5, Wood discloses wherein each of said first or second nasal inserts (22, 30) has a characteristic length (Fig. 2A); the length of either the first or second nasal insert are sufficiently long to allow an insert to move in the nasal passage until the cross section area of the nare and the cross section of said nasal insert, are substantially the same, thereby forming a positive pressure seal between said nasal insert and said nare (Col. 6, lines 30-67 and Col. 7, lines 1-54).

With respect to claim 6, note rejection of claims 1, 3, and 4 above.

With respect to claim 7, Wood discloses the one or more bleed ports having an internal lumen (Fig. 4); the one or more bleed ports located directly in line with one of the two nasal inserts (Figs. 1-6) for preferentially intercepting expired gas during an exhalation, the one or more bleed ports having a characteristic bleed port diameter called BPD. With respect to calling the bleed port diameter BPD, such would have been an obvious matter of design consideration as BPD is an acronym for bleed port diameter; also calling the distance between bleed ports L, one of ordinary skill in the art at the time the invention was made would find it an obvious matter of design consideration to call the distance between the bleed ports as L because L represents a term for length well known in the art.

With respect to claim 8 and the bleed port diameter between 3/8 inches and 5/8 inches, it would have been obvious to one of ordinary skill in the art at the time the invention was made, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. As long at the limitations of the bleeder port being able to permit venting of carbon dioxide exhaled by the patient while not being so large as to cause a significant pressure drop in the cannula body as disclosed by Wood (Col. 7, lines 21-35).

With respect to claim 9, Wood discloses wherein the two nasal inserts terminate in compliant flanges at their distal ends to conform to the nare of a patient (22).

With respect to claim 10, note rejection of claim 5 above.

With respect to claim 11, note rejection of claim 1 above.

With respect to claim 12, Wood discloses wherein the at least one bleed port communicates with the first and second delivery tubes and opens to atmospheric pressure (38).

With respect to claim 13, Wood discloses wherein the at least one bleed port is substantially linearly aligned with one of the first nasal insert or second nasal insert (Figs. 1-6).

With respect to claim 14, note rejection of claim 8 above.

With respect to claim 15, note rejection of claim 3 above.

With respect to claim 16, it would have been obvious to one of ordinary skill in the art that where there is no indentation the cannula would be more rigid as there would be a thinner area at any indentation.

With respect to claim 17, note rejection of claim 9 above.

With respect to claim 18, Wood discloses wherein the nares of a patient will deform the shape of the first and second nasal inserts (30) and their compliant flanges (36) to form a seal between the nasal cannula and the nares of the patient (Col. 6, lines 21-67).

With respect to claim 19, Wood discloses wherein the length of either the firs or second nasal insert are sufficiently long to allow an insert to move in the nasal passage until the cross section are of the nare of a patient and the cross section area of the nasal insert are substantially the same, thereby forming a positive pressure seal between said nasal insert and said nare (Col. 6, lines 21-67).

With respect to claim 20, Wood discloses wherein the coupler is y-shaped (12).

Response to Arguments

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teena Mitchell
Examiner
Art Unit 3743
August 22, 2005

TKM